

CLAIMS

1. A material for medical use in humans and/or animals bearing a biologically active agent, said material being multilayered comprising

5 a) a core material, wherein said core material is formed into a body, optionally into a body having the shape of a finished device,

b) two or more layers of coating material of which the first layer has been applied onto said core material and additional layers have been applied onto said coating material of a preceding layer and

10 c) said biologically active agent incorporated in at least one of the coating layers,

characterized in that said coating material is a biopolymer, a sol-gel produced silica gel or a biologically active molecule.

2. The material according to claim 1 **characterized** in that the core material is a biodegradable silica body, e.g. bioactive glass or sol-gel produced silica gel, or a
15 biopolymer, e.g. a polylactide or a cellulose.

3. The material according to claim 1 or 2, **characterized** in that said coating material is a biopolymer, e.g. a polylactide or a cellulose.

4. The material according to claim 1 or 2, **characterized** in that said coating material is a sol-gel produced silica gel.

20 5. The material according to claim 1 or 2, **characterized** in that said coating material is heparin.

6. The material according to any of the claims 1 to 5, **characterized** in that a biologically active agent is composed in a sol-gel produced silica gel body or a sol-gel produced silica gel coating layer, or a biopolymer body or biopolymer coating layer.

5 7. The material according to any of the claims 1 to 6, **characterized** in that the core material and all coating materials are biodegradable.

8. The material according to any of the claims 1 to 7, **characterized** in that it is a body in the shape of a granule, spherulite, sheet, film, plate, stick, pin, screw, tube, fiber, hollow fiber, woven fabric or non-woven fabric or the like also when built to
10 resemble human or animal body parts such as ear, nose, joints etc. or parts thereof.

9. The material according to claim 8, **characterized** in that it is shaped to a stent, dental or orthopedic implant; implant for controlled drug delivery; bone fixation pin, fixation plate, regeneration matrix, or the like also when built to resemble human or animal body parts such as ear, nose, joints etc. or parts thereof.

15 10. The material according to any of the claims 1 to 9, **characterized** in that the biologically active agent is a polypeptide, a protein, a polysaccharide, an oligosaccharide, a mono- or disaccharide, an organic compound, an organometallic compound or an inorganic compound containing any element with an atomic number ranging from 3 to 84.

20 11. The material according to claim 10, **characterized** in that the biologically active agent is

- an inorganic ion or a polymer thereof,
- silica gel as such or silica gel loaded with a therapeutical agent,
- heparin or its derivative,
- 25 - a growth factor,

- a growth factor producing virus,
- a growth factor inhibitor,
- an integrin blocker (e.g. a IIa/IIIb inhibitor)
- an oligonucleotide or
- 5 - a complete functional or partial gene in sense or antisense orientation in a suitable expression vector or any other expression vector construct

for local delivery of said biologically active agent.

12. The material according to claim 9, **characterized** in that it is shaped to a stent, the inner wall of which is provided with a biologically active agent; which is

- 10 - an inorganic ion or a polymer thereof,
- silica gel as such or silica gel loaded with a therapeutical agent,
- heparin,
- a growth factor,
- a growth factor producing virus,
- 15 - a growth factor inhibitor,
- an integrin blocker (e.g. a IIa/IIIb inhibitor),
- an oligonucleotide or
- a complete or partial functional gene in sense or antisense orientation in a suitable expression vector or any other expression vector construct; and

20 which biologically active agent is released at a controlled rate in *in vivo* conditions.

13. A device made of a material, useful for finishing into a device of a material for medical use in humans and/or animals, said material bearing or being capable of binding a biologically active agent, wherein said material is multilayered and formed into a body of the shape of a finished device comprising

- 25 a) a core material, wherein said core material is formed into a body, optionally into a body having the shape of a finished device,

b) two or more layers of coating material of which the first layer has been applied onto said core material and additional layers have been applied onto said coating material of a preceding layer and

c) at least one layer of coating material capable of binding a said biologically active agent

characterized in that said coating material is a biopolymer, a sol-gel produced silica gel or a biologically active molecule.

14. A method for the preparation of a multilayered material for medical use in humans and/or animals bearing a biologically active agent, said material comprising

a) a core material, wherein said core material is formed into a body, optionally into a body having the shape of a finished device,

b) two or more layers of coating material of which the first layer has been applied onto said core material and additional layers have been applied onto said coating material of a preceding layer and

c) said biologically active agent incorporated in at least one of the coating layers, and

wherein said coating material is a biopolymer, a sol-gel produced silica gel or a biologically active molecule, **characterized** by the repeated steps of

i) coating said core material or a coating material of a preceding layer with a coating material which optionally can comprise a biologically active agent and

ii) optionally binding a biologically active agent to the said coating.

15. The method according to claim 14 wherein the core material has been formed into a body, optionally into a body having the shape of a finished device, **characterized** in that a coating is generated on the core material or a coating material of a preceding layer on a desired region of the body.

16. The method according to claim 14 or 15, **characterized** in that the attachment of a coating layer is improved by using surface modification techniques of the surface to be coated, i.e. the core surface or the surface of the previous coating layer.

- 5 17. The method according to claim 16, **characterized** in that the surface modification technique used is radiation induced grafting or silylation treatment.

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